K001465
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DEC - 5 2000

510(k) Summary of Safety and Effectiveness

1. **Manufacturer and Contact Information:**

Manufacturer	Nissho Nipro Corporation Ltd. 10/2 Moo 8, Bangnomko, Sena Ayutthaya, Thailand 13110
U. S. Distributor	Nipro Medical Corporation 3150 N. W. 107 Avenue Miami, FL 33172
Contact Information	Richard D. Bliss, Jr. Quality Systems Engineering 510 Stonemont Drive Weston, FL 33326 Telephone: (954) 385-1690 Fax: (954) 385-1256

2. **Device Classification Name:**
The Gastroenterology Devices Panel has classified Hemodialysis system and accessories as Class II. Reference 21 CFR 876.5820.

3. **Intended Use:**
The Nipro Blood Tubing Set for Hemodialysis with Transducer Protector and Priming Set is intended are disposable bloodlines intended to provide extracorporeal access to the patient's blood during hemodialysis. The compatibility of available configurations is the responsibility of the physician.

4. **Device Description and Characteristics**
This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) 1990.

The Nipro Blood Tubing Set for hemodialysis with or without Transducer Protector and Priming set includes arterial and venous dialysis blood tubing (non-implanted blood access device) as described in 21 CFR 876.5820. The blood tubing sets have previously been described in detail as part of Premarket Notifications, cleared by the FDA under K954676, K972493, and K972206.

The arterial and venous blood tubing sets include din this 510(k) are modifications of Nipro Blood Tubing Set for hemodialysis with transducer protector and priming set, K972206. The modification includes the use of a different brand of transducer protector previously cleared by FDA in K983076.

The devices are packaged together for convenient use during the hemodialysis procedures. There are 26 series of arterial line (A201 – A211, A213 – A214, A301 – A311, A313 – A314) and 10 series of venous line (V801 – V805 and V901 – V905). The packaging configurations are of paired and single sets, with or without priming sets and transducer protectors.

The various blood set models are being manufactured for application with various models of dialysis machines. The components of the device include tubing, drip chambers, infusion tubing, pressure monitoring lines, ports, clamps, and filters which are used to pump blood, retain and capture blood debris, infuse medications or fluids, sample blood, monitor pressure, and make connections to other devices. Materials used for the various components in this device include Polyvinylchloride (PVC), Polyethylene (PE), Polycarbonate (PC), Polypropylene (PP), and Polyoxymethylene (POM), and others.

The devices are packaged sterile and labeled for single use only. There is no ability to clean and reuse these devices. They are restricted for sale by or on the orders of a physician. The results of biocompatibility data support the equivalence of the predicate devices and include pyrogenicity, acute toxicity, intracutaneous reactivity, hemolysis testing, implantation testing, and sterility testing.

5. Substantial Equivalence

Nipro Medical Corporation considers the modified Nipro Blood Tubing Set for Hemodialysis with Transducer Protector and Priming Set to be substantially equivalent to the existing Nipro Blood Tubing Set for Hemodialysis with Transducer Protector and Priming Set and the Medisystems Arterial – Venous Blood Tubing Sets with regard to intended use, materials, biocompatibility, and overall performance characteristics. The labeling is equivalent to the predicate devices in intended use, components and materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 5 2000

Nipro Medical Corporation
c/o Richard D. Bliss, Jr.
President
Quality Systems Engineering, Inc.
510 Stonemont Drive
WESTON FL 33326

Re: K001465
Nipro® Blood Tubing Set for Hemodialysis with Transducer Protector and Priming Set
Dated: September 6, 2000
Received: September 6, 2000
Regulatory Class: II
21 CFR §876.5820/Procode: 78 FIB and 78 FJK

Dear Mr. Bliss:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Device Name: Nipro® Blood Tubing Set with Transducer Protector and Priming Set

Indications for Use:

The Nipro® Blood Tubing Set with Transducer Protector and Priming Sets are disposable bloodlines intended to provide extracorporeal access to the patient's blood during hemodialysis. The compatibility of available configurations is the responsibility of the physician in charge.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___√___ (Pre 21 CFR 801.109) or Over-The-Counter Use_____ (Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K001465